

Introduction

Transplantation is the procedure involving the removal of a bodily organ or tissue from one person, and the insertion of that organ or tissue into another person to replace a damaged organ or tissue.

Definition of Terms:

Allograft – transplant from one individual to another (synonymous with homograft)

Hereotopic graft – transplant placed in a site different than the organ's normal location

Orthotopic graft – transplant placed in its normal anatomical site

Syngeneic graft (isograft) – transplant between identical twins

Xenograft – transplant between different species

Organ transplantation is now well established as an effective treatment for selected patients with end-stage organ failure. Transplantation of the kidney, liver, pancreas, heart, and lungs are all routine procedures, and transplantation of the small intestine is becoming more widely practiced. Currently, transplant activity is limited only by the shortage of cadaveric organs.

The following policy contains the minimal criteria for solid organ transplants. Additional justification may be required at the discretion of the Division of Medical Assistance Hospital Consultant staff.

1.0 Description of the Procedure

Kidney transplant is a procedure to implant a healthy kidney into a patient with a diseased or failing kidney. The donor kidney may come from a living donor or recently deceased donor.

2.0 Eligible Recipients

2.1 General Provisions

Medicaid eligible individuals with a need for this specialized treatment confirmed by a licensed physician are eligible as long as they meet individual eligibility requirements. Medicaid recipients may have service restrictions due to their eligibility category, which would make them ineligible for this service.

2.2 Special Provisions

Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) is a federal Medicaid requirement that provides recipients under the age of 21 with medically necessary health care to correct or ameliorate a defect, physical or mental illness or a condition identified through a screening examination. While there is no requirement that the service, product or procedure be included in the State Medicaid Plan, it must be listed in the federal law at 42 U.S.C. § 1396d(a). Service limitations on scope, amount or frequency described in this coverage policy do not apply if the product, service or procedure is medically necessary.

The Division of Medical Assistance's policy instructions pertaining to EPSDT are available online at <http://www.dhhs.state.nc.us/dma/prov.htm>.

3.0 When the Procedure is Covered

Each recipient's condition is evaluated on an individual basis. There may be other conditions that are indications for coverage.

3.1 Coverage Criteria

The N.C. Medicaid program covers kidney transplants for patients with the following conditions after their creatinine clearance calculated by the Cockcroft-Gault formula is 30ml/min (not all inclusive):

1. obstructive uropathy
2. hemolytic uremic syndrome
3. acute tubular necrosis
4. hypertensive nephrosclerosis
5. systemic lupus erythematosus
6. polyarteritis
7. Wegener's granulomatosis
8. cortical necrosis
9. renal artery/vein occlusion
10. chronic pyelonephritis
11. Henoch-Schonlein purpura
12. IGA nephropathy
13. diabetes
14. polycystic kidney disease
15. anti-glomerular base membrane disease
16. focal glomerulosclerosis
17. analgesic nephropathy
18. heavy metal poisoning
19. nephritis
20. amyloid disease
21. Fabry's disease
22. Cystinosis
23. oxalosis
24. horseshoe kidney
25. Wilms tumor
26. myeloma
27. renal aplasia/hypoplasia
28. renal-cell carcinoma
29. trauma requiring nephrectomy
30. sickle cell disease
31. scleroderma
32. urolithiasis
33. tuberous sclerosis

3.2 Donors

Donor expenses (**procuring, harvesting, and associated surgical and laboratory costs**) **are** covered for a kidney transplant, if 1) the transplant recipient has received prior approval, and 2) where living donor transplantation is indicated, the donor is a **Medicaid** recipient. In all other circumstances the donor expenses **are not** covered.

4.0 When the Procedure is Not Covered

Kidney transplants are not covered when the medical necessity criteria listed in **Section 3.0** are not met. Each recipient's condition is evaluated on an individual basis. There may be other conditions that are indications for non-coverage.

The N.C. Medicaid program does not cover kidney transplants when one of the following conditions exists (not all inclusive):

4.1 Absolute

1. HIV positive
2. active malignancy
3. untreated or irreversible end-stage illness
4. active vasculitis
5. active infection
6. alcohol abuse within last 12 months
7. history of or active substance abuse – must have documentation of substance abuse program completion plus six months of negative sequential random drug screens

Note: To satisfy the requirement for sequential testing as designated in this policy, the Division of Medical Assistance (DMA) must receive a series of test (alcohol and drug) results spanning a minimum six-month period, allowing no fewer than a three-week interval and no more than six-week interval between each test during the given time period. A complete clinical packet for prior approval must include at least one documented test performed within one month of the date of request to be considered.

8. current patient and/or caretaker non-compliance that would make compliance with a disciplined medical regime improbable
9. psychosocial history that would limit ability to comply with medical care pre and post transplant

4.2 Relative

1. age more than 70 years
2. cardiovascular disease and risk (EF < 40%)
3. chronic liver disease (chronic hepatitis B or C)
4. progressive pulmonary disease

5.0 Requirements for and Limitations on Coverage

All applicable N.C. Medicaid policies and procedures must be followed in addition to the ones listed in this policy.

All procedures must be prior approved by DMA.

6.0 Providers Eligible to Bill the for Procedure

Physicians enrolled in the N.C. Medicaid program who perform this procedure may bill for this service.

7.0 Additional Requirements

FDA approved procedures, products, and devices for implantation must be utilized.

Implants, products, and devices must be used in accordance with all FDA requirements current at the time of surgery.

A statement signed by the surgeon certifying all FDA requirements for the implants, products, and devices must be retained in the recipient's medical record and made available for review upon request.

8.0 Policy Implementation/Revision Information

Original Effective Date: July 1, 1987

Revision Information:

Date	Section Revised	Change
7/1/05	Entire Policy	Policy was updated to include coverage criteria effective with approved date of State Plan amendment 4/1/05.
9/1/05	Section 2.2	The special provision related to EPSDT was revised.
12/1/05	Section 2.2	The web address for DMA's EDPST policy instructions was added to this section.

Attachment A Claims Related Information

Reimbursement requires compliance with all Medicaid guidelines including obtaining appropriate referrals for recipients enrolled in the Medicaid Managed Care programs.

A. Claim Type

1. Physicians bill professional services on the CMS-1500 claim form..
2. Hospitals bill for services on the UB-92 claim form.

B. Diagnosis Codes that Support Medical Necessity

Providers must bill the ICD-9-CM diagnosis code to the highest level of specificity that supports medical necessity.

C. Procedure Codes

Codes that are covered under the kidney transplant include:

50300	50320	50340	50360	50365	50380
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D. Providers must bill their usual and customary charges.

E. Billing for Donor Expenses

Living donor expenses are billed on the donor claim.